Translation

PATENT COOPERATION TREA

PCT/JP2003/015503

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

Rec'd PCT/PTO 03 JUN 2005

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT-A0342-00	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/015503	International filing date (*day/month/year*) 04 December 2003 (04.12.2003)	Priority date (*day/month/year*) 04 December 2002 (04.12.2002)
International Patent Classification (IPC) or national classification and IPC A61K 45/00, 31/7056, 31/706, A61P 3/04, 43/00		
Applicant KISSEI PHARMACEUTICAL CO., LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29 June 2004 (29.06.2004)	26 November 2004 (26.11.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/015503

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

national application No.
PCT/JP03/15503

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 9-16

because:

☒ the said international application, or the said claims Nos. 9-16 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

Claims 9-16 relate to methods for treatment of the human body by therapy.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 9-16.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1, 3-8, 17, 19-24	YES
	Claims	2, 18	NO
Inventive step (IS)	Claims	1, 3-8, 17, 19-24	YES
	Claims	2, 18	NO
Industrial applicability (IA)	Claims	1-8, 17-24	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: Polyphenol-Induced Inhibition of the Response of Na^+/Glucose Cotransporter Expressed in Xenopus Oocytes, (Sheikh Julfikar Hossain, et al.), Journal of Agricultural and Food Chemistry, 2002, Vol. 50, No. 18, pages 5215-5219

Document 2: Acute Increase, Stimulated by Prostaglandin E_2, in Glucose Absorption via the Sodium Dependent Glucose Transporter-1 in Rat Intestine, (B. Scholtka, et al.), Gut, 1999, Vol. 44, No. 4, pages 490-496

Document 3: Increased Intestinal Glucose Absorption and Postprandial Hyperglycemia at the Early Step of Glucose Intolerance in Otsuka Long-Evans Tokushima Fatty Rats, (Y. Fujita, et al.), Diabetologia, 1998, Vol. 41, No. 12, pages 1459-1466

Document 4: Expression of Glucose Transporters in Human Peritoneal Mesothelial Cells, (B. Schröppel, et al.), Kidney International, 1998, Vol. 53, No. 5, pages 1278-1287

Novelty and inventive step:

Claims 1, 3-8, 17 and 19-24

Document 1 describes that catechins, which are SGLT inhibitor drugs, inhibit the intake of glucose, so such inhibitor drugs can be used for diabetic patients (page 5215, abstract).

Document 2 describes that phlorizin, which is a selective SGLT inhibitor drug, inhibits the absorption of glucose (page 490, abstract, Fig. 3).

Document 3 describes that phlorizin controls the rise in blood sugar level after a glucose load (page 1459, abstract).

Document 4 describes that phlorizin inhibits the intake of glucose derivatives (page 1278, abstract).

Accordingly, the subject matters of claims 1, 3-8, 17 and 19-24 do not appear to be novel or to involve an inventive step in view of documents 1-4.

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO 04/014932 A1 [E, X]	19.02.2004	07.08.2003	08.08.2002
WO 02/098893 A1 [E, X]	12.12.2002	27.05.2002	30.05.2001

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 2 and 18 of the present application describe "a preventive or remedy agent described in claim 1 that is an SGLT inhibition agent whose active ingredients do not substantially show a GLUT2 and/or GLUT5 inhibition effect", but the specification of the present application concretely discloses only the compounds described in Examples 1 and 2 as compounds having the above-mentioned characteristic.

It is not considered that any other compound having the above-mentioned characteristic was well known to a person skilled in the art at the time of filing of the present application. Accordingly, the subject matters of claims 2 and 18 wherein the active ingredients are compounds other than the above-mentioned two ones are not adequately supported by the specification.